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December 15, 2021

VIA ECF AND EMAIL

The Honorable Robert B. Kugler
United States District Court Judge
District of New Jersey
Mitchell H. Cohen Building & U.S.
Courthouse
4th & Cooper Streets, Room 1050
Camden, NJ 08101

**Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, Case
No. 1:19-md-02875-RBK: Defendants' Position Regarding the Appointment
of Separate Settlement Counsel**

Dear Judge Kugler:

We write to provide the Court with Defendants' response to the Court's suggestion that the parties consider the appointment of separate outside settlement counsel, which is a topic the Court raised during the Case Management Conference on December 1, 2021.

Defendants are amenable to, and some have already implemented, designating counsel within the firms currently representing Defendants in this MDL, but who have not been "in the trenches" in terms of the day-to-day litigation, to take a prominent role in any settlement negotiations. Defendants respectfully suggest that Plaintiffs likewise be encouraged to make similar designations, as such counsel could achieve what we understand to be the Court's aim of having more objective voices, on both sides, negotiating, while, at the same time, avoiding what would most certainly be a prohibitively expensive and time-consuming process of vetting, retaining, and bringing up to speed scores of law firms and lawyers all of whom would be new to these complex proceedings.

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Defendants have been, and it is our understanding that Plaintiffs also have been, following the settlement negotiation process that has been implemented by the settlement masters, including Defendants having just recently conducted a full-day meeting with Judges Stengel and Sleet on November 17, 2021, relating to general causation. At the conclusion of that meeting the settlement masters agreed to conduct another session with Defendants in early 2022 to discuss the complexities surrounding class certification. Given the parties' current involvement with the settlement masters, and Defendants' intention (we expect the same of Plaintiffs) to continue to participate in the settlement process they implement, the appointment of separate outside settlement counsel is not necessary and would in fact likely impede the settlement process.

The appointment of separate outside settlement counsel would also result in an extremely expensive and disruptive process of educating counsel new to the matter on the complex factual and legal issues pertaining to the merits of Plaintiffs' claims and Defendants' defenses, which would necessarily be required to fairly negotiate a resolution of this matter. Further, it is anticipated that the retention of additional counsel by the more than 50 Defendants would not be easily accomplished, and would cause significant practical problems.¹ It would require an extraordinary amount of time for counsel new to this case to familiarize themselves with the intricacies of the highly technical pharmaceutical manufacturing and pharmaceutical regulatory issues set forth in the more than 150 depositions and tens of millions of pages of documents and dispensing records that comprise the factual and expert record in this case. Over the next several months the parties will be engaged in 15-20 class certification expert depositions and briefing on Plaintiffs' three class certification motions, which proceedings will be unquestionably and significantly hampered, if not entirely derailed, by the onboarding of new law firms and lawyers who have to be trained in this case to fairly negotiate a settlement. Sidetracking these proceedings and imposing such expense on the parties when counsel at law firms already of record, who can benefit from the institutional knowledge their firms possess about the facts and law at issue, can be, and in some cases already have been, designated to take a prominent role in any settlement negotiations would be unwarranted.

Given that counsel from the law firms already involved in the MDL are well-versed in the facts and the complex issues integral to this matter, affirming Defendants' choice to have those counsel very meaningfully involved in any settlement negotiations, as opposed to appointing separate outside settlement counsel, would enable the parties and the settlement masters to efficiently measure the value of Plaintiffs' claims and the risks of litigation to the Defendants against the pertinent facts, law, and liability issues. In contrast to any newly appointed separate settlement counsel, defense counsel of record have reviewed the tens of millions of pages of

¹ This is especially true for those multi-national Defendants whose corporate headquarters and leadership are in other countries, and who might not be familiar with U.S. law firms that could assume the role of separate outside settlement counsel. As a practical matter, such appointment could become a distraction for the parties and counsel of record and would increase the amount of resources necessary to engage in settlement discussions by requiring a lengthy vetting process by Defendants of any new law firms and counsel, which process would necessarily involve counsel of record.

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documents and dispensing records, taken and defended the more than 150 fact and expert depositions, and analyzed the vast body of law at issue. Respectfully, it would be fundamentally unfair and prohibitively expensive to require Defendants to retain new counsel with no prior involvement in this case, and to obligate them to pay those counsel to get educated in order to be able to adequately represent their interests in settlement discussions.

The parties' designation of counsel at the law firms currently representing them in the MDL, who are not "in the trenches," in terms of the day-to-day litigation, to have a prominent role in any settlement negotiations in this matter would be more efficient, productive, and less expensive than appointing separate settlement counsel, while also putting lawyers who may be more objective than those in the trenches around the negotiating table, and such choice of counsel by the parties should be afforded deference. Of note here is the fact that while the Manual for Complex Litigation, and orders in other multi-district litigation, acknowledge that a court may "consider *suggesting* that one or more of the parties engage or designate special settlement counsel separate from lead and liaison counsel," see *Manual for Complex Litig.*, Fourth § 13.13, requiring the parties "to retain separate settlement counsel" is "something the court is without authority to do." *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 16-md-2734 (N.D. Fla. Oct. 25, 2016), ECF No. 607; see also *In re Depakote: Alexander, et al. v. Abbott Labs., Inc.*, 12-CV-52-NJR-SCW (N.D. Ill. July 6, 2016), ECF No. 485 (directing, in an MDL involving approximately 700 plaintiffs, that parties are "*strongly encouraged* to retain independent, separate settlement counsel," but not ordering appointment of such counsel) (emphasis in original).

In actuality, the advancement of the settlement process on which the parties – at least Defendants – have embarked with the settlement masters has tracked the progression of the MDL proceedings. The parties have been working since July 2020 producing the tens of millions of documents and dispensing records; taking and defending more than 150 depositions of personal injury bellwether plaintiffs and their physicians, class representatives, and defendant fact and corporate witness depositions; submitting 14 expert reports on general causation; taking and defending the depositions of those experts; and briefing 12 Rule 702 of motions, the replies for which are due in the coming weeks. And Plaintiffs' three class certification motions, accompanied by nine expert reports, were filed in early November and will be fully briefed in the coming months, after the parties complete the deposition of Plaintiffs' class certification experts and the depositions of any class certification experts the Defendants rely upon. It cannot be reasonably disputed that the development of such a comprehensive factual and expert record was and is necessary before the parties – *and the settlement masters* – can fairly weigh the value of Plaintiffs' claims against the strength of Defendants' defenses.

Moreover, in the coming months issues critical to valuing Plaintiffs' claims, including potentially disposing of some, if not all, of them, are to be decided. As this Court has recognized, if Plaintiffs cannot demonstrate as a threshold matter that the trace levels of nitrosamines at issue are capable of increasing the risk of the cancers alleged, then Plaintiffs do not have a case – neither as to personal injury, or as to economic loss or medical monitoring. See 3/27/19 Tr. at 6:9-16; 11/24/20 Tr. at 12:18-22. Defendants' Rule 702 motions relating to Plaintiffs' general causation will be fully briefed and *sub judice* by January 6, 2022.

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Even if Plaintiffs could overcome the initial hurdle of establishing general causation, it is far from a foregone conclusion that any class in this case would actually be certified. Plaintiffs' attempt at class certification appears fraught with debilitating issues, such as, for example, proposing 93 *sub-classes* for the consumer economic loss plaintiffs alone, each of which is comprised of a panoply of combinations of defendants, claims, and state laws, *see* ECF 1747-1 (for example, a subclass involving only defendants ZHP, Torrent, and Teva as to only express warranty claims under the laws of 30 states whose laws Plaintiffs contend do not conflict with the laws of states with a putative class representative, and 92 other similarly constructed subclasses), and suggesting that all 93 proposed sub-classes can be tried in a single, joint bench/jury trial. *See* ECF 1748-23.

The Court also will be resolving both sides' objections to Special Master Vanaskie's report and recommendation regarding Plaintiffs' motion for leave to amend their master complaints. Given the vastly different circumstances of the dozens of Defendants spanning the different pharmaceutical supply chain levels with respect to the alleged nitrosamine impurities and the claims for which they could plausibly be liable, settlement negotiations should be among those Plaintiffs and those Defendants who actually have claims or exposure and are brought within the Court's jurisdiction² under an operative pleading.

Although Plaintiffs, who have never made any settlement demand, may complain that Defendants have not engaged with them in any direct negotiations, where, as here, the alleged damages are in the many billions of dollars, Defendants should not, in the interest of swiftness, simply be expected to settle without the development of the factual record necessary to fairly value Plaintiffs' claims, without the Court's views on general causation and class certification, and without operative pleadings that provide the framework of parties and claims that may settle and be resolved.

Defendants certainly acknowledge and have already meaningfully acted upon the Court's desire for the parties to determine whether a path toward the amicable resolution of this case can be established, and Defendants are certainly open to, anticipate, and look forward to continuing to meet with the settlement masters in this regard. Defendants are amenable to designating counsel from the firms representing them in the MDL who are not "in the trenches" in terms of the day-to-day litigation to have a prominent role in any settlement negotiations and, in fact, as the settlement masters are aware, such a process has already begun in earnest. Likewise, Defendants respectfully request the Court encourage Plaintiffs to do as Defendants are doing, and designate counsel within their firms already representing Plaintiffs in the MDL, who are not "in the trenches," to take a prominent role in any settlement negotiations on Plaintiffs' behalf.

In Defendants' view, the designation of such counsel by both sides, as opposed to any formal or required appointment of settlement counsel separate and apart from the law firms who

² Defendants, who include a number of foreign corporations, have also reserved their right to challenge personal jurisdiction; the Court has not yet made any such jurisdictional ruling. ECF No. 520-3, at 9 n.12.

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the parties have chosen to represent them and who are the most familiar with the facts and legal issues in this case, would be the most expedient, efficient, and fair way to proceed in exploring an amicable resolution of this matter.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Defendants' Executive Committee (via email)